

JUL - 8 2008

**SPECIAL 510(K) SUMMARY**  
**BIRTHTRACK SYSTEM**

**510(k) Number K080672**

**Applicant's Name:** Barnev Ltd.  
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Israel  
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**Date Prepared:** March 2008

**Trade Name:** BirthTrack™ Continuous Labor Monitoring (CLM) System

**Classification Name:** NPB

**Classification:** Class II medical Device

**Predicate Device:** The BirthTrack System is comparable to the following predicate devices:

- CLM, Computerized Labor Monitoring system (K060028) manufactured by Barnev. The BirthTrack is a name change of the CLM system, and the changes from the approved CLM system lies in its accessories, the Fetal Spiral Sensor and the Cervical Sensor.
- The Cervical Sensor is comparable to the Disposable FSE (K844608) manufactured by Surgicraft Copeland, and to the previous Cervical ITR (K060028) manufactured by Barnev.

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- The Fetal Spiral Sensor is comparable to the Disposable FSE (K030691) manufactured by Clinical Innovations, and to the previous Fetal ITR (K060028) manufactured by Barnev.

**Device Description:** Barnev's BirthTrack system uses ultrasound technology to provide measurements of cervix dilatation and fetal head station. Signals from disposable sensors located on the maternal cervix and fetal head provide objective and continuous cervical dilatation and fetal head station data, reducing the need for frequent vaginal examinations.

**Intended Use / Indication for Use:** The BirthTrack System is an ultrasound device intended to be used for monitoring the active phase of labor in women with term pregnancies, vertex presentation, and ruptured membranes. It is intended to be placed when cervical dilation is between 3 cm and 7 cm. The device continuously measures cervical dilation and fetal head station with ultrasound transducers attached to the maternal abdomen and cervix and to the fetal scalp. These measurements are displayed numerically and graphically as a function of time to show the progress of labor.

**Performance Standards:** The BirthTrack System complies with:  
U.S. Federal Performance Standard set forth in 21 CFR 898 for electrode lead wires and Patient Cables.

In addition, the device complies with the recognized standards: It also complies with ISO 11137, IEC-60601-1 and amendments, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37 and AAMI/ANSI/ISO 10993-1.

**Substantial Equivalence:** Based on bench studies and clinical evaluation, we believe that the Birthtrack System and their accessories are low risk devices. Moreover, the risks imposed by the Birthtrack system and its accessories are lower or equal to these imposed by the predicate devices and standards medical practice. The performance of the Birthtrack system is substantially equivalent to the performance of its predicate device cited above and to these of manual procedures.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

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A.Stein Regulatory Affairs Consulting  
c/o Ms. Ahava Stein  
Barnev Ltd.  
20 HATA'AS ST.  
KFAR SABA  
ISRAEL 44425

Re: K080672  
Trade Name: BirthTrack™  
Regulation Number: 21 CFR 884.2800  
Regulation Name: Computerized Labor Monitoring System  
Regulatory Class: II  
Product Code: NPB  
Dated: June 13, 2008  
Received: June 17, 2008

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

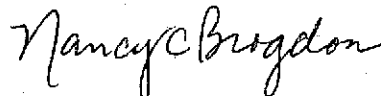
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## SECTION 1 – INDICATION FOR USE

510(K) Number (if known): K080672

Device Name: BirthTrack™

**Indication for use:** The BirthTrack System is an ultrasound device intended to be used for monitoring the active phase of labor in women with term pregnancies, vertex presentation, and ruptured membranes. It is intended to be placed when cervical dilation is between 3 cm and 7 cm. The device continuously measures cervical dilation and fetal head station with ultrasound transducers attached to the maternal abdomen and cervix and to the fetal scalp. These measurements are displayed numerically and graphically as a function of time to show the progress of labor.

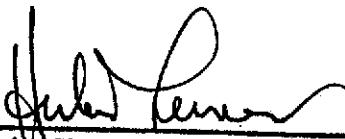
Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over the Counter Use ☐

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

510(K) Number K080672

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K080672